The U.S.-Australia Free Trade Agreement's Unfortunate Attack on Good Healthcare Policy

Kevin Outterson*

1. The Australian Pharmaceutical Benefits Scheme

Americans are increasingly looking to "pay for value" in health care. The Australian experience with the economic evaluation of drugs in the Pharmaceutical Benefits Scheme (PBS) is the gold standard of such programs worldwide. The PBS is not government price controls, but allows pharmaceutical companies to request higher reimbursement levels if data establishes the greater cost-effectiveness of the drug. It does not appear that Australia is 'free riding' on American-funded innovation, since companies are given ample opportunity to seek higher reimbursement for truly innovative drugs.

The PBS has generated unwelcome attention from PhRMA and its Australian counterpart, Medicines Australia. This is unsurprising, since the PBS economic evaluations have resulted in some of the lowest patented drug prices in the OECD, much lower than even Canadian prices.[1] After years of unsuccessful domestic attempts to derail PBAC in Australia, PhRMA and Medicines Australia turned to international trade law, namely the Australian-US Free Trade Agreement (FTA). The primary talking point on this issue is to increase transparency in the PBS (see section 5 below), but the actual goal is to increase Australian drug prices.

2. The FTA is Likely To Raise Australian Drug Prices

A debate is underway in Australia as to whether the FTA will force significant changes in PBS.[2] While scaled back from early proposals, the FTA nonetheless requires subtle modifications to the PBS which will lead to higher prices in Australia, as detailed by a

* Associate Professor of Law, West Virginia University College of Law, Kevin.Outterson@mail.wvu.edu.
[1] The data on lower prices in Australia was collected by the Productivity Commission, International Pharmaceutical Price Differences (July 2001). The Productivity Commission did not reach a definitive conclusion on causation.
[2] Over the past year, hundreds of articles on the FTA's impact on the PBS have appeared in the Australian press. In the US, the issue barely rates a whisper. Most US coverage of the FTA concerns agriculture such as sugar and beef. Prior to May 2004, very few serious discussions of the PBS issue have appeared in the U.S. national press. But see E. Becker, Overseas Drug Prices Targeted By Industry; U.S. Officials Pressure Australia On Controls, N.Y. Times A1 (Nov. 27, 2003); M.W. Serafini, Drug Prices: A New Tack, 36:16 National Journal (Apr. 17, 2004); M.W. Serafini, The Other Drug War, 36:12 National Journal (Mar. 20, 2004).

recent editorial in the British Medical Journal[3] and recent testimony in the Australian Parliament.[4]

Against this evidence, the Australian government claims that the FTA provisions won't raise drug prices at all in Australia.[5] If that is so, then why did PhRMA and Medicines Australia fight for the provision? If there is truly no impact on drug prices, then it should be removed immediately by a side letter.

A similar non-sequitur arose under the 'non-interference' provision PhRMA added to the Medicare Modernization Act of 2003.[6] This law commits the US federal government to purchase US$ 600 billion in pharmaceuticals over the next decade,[7] but prohibits the government from using its purchasing power to negotiate better prices. The Bush Administration insists that this provision won't affect the price at all.[8]

The US negotiated the FTA under the assumption that drug prices in Australia are too low and must be increased.[9] Other observers might reach the opposite conclusion: that

---

[3] P. Drahos & D. Henry [Editorial] The free trade agreement between Australia and the United States: Undermines Australian public health and protects US interests in pharmaceuticals. BMJ 2004; 328:1271-1272 (29 May), http://bmj.bmjjournals.com/cgi/content/full/328/7451/1271?etoc.

[4] See the submissions by the Generic Medicines Industry Association Pty Ltd., the Doctors Reform Society, the Public Health Association of Australia, Inc., the Australian Nursing Federation, Catholic Health Australia, the National Center for Epidemiology and Population Health, the Australian Consumers' Association, and Dr. Ken Harvey, all available at: http://www.aph.gov.au/Senate/committee/freetrade_ctte/index.htm.

[5] L. Tingle, New Analysis Backs Benefits of Trade Deal, Australian Financial Review 7 (May 1, 2004) ("The report says there will be no material impact on the price of drugs from a clause in the pact which gives US drug companies the right to challenge decisions of the Pharmaceutical Benefits Advisory Committee.").

[6] Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, § 301 (codified at § 1808(c)(1)(C) of the Social Security Act).

[7] CBO, *Estimate on H.R. 1* (Congressional Budget Office, Nov. 20, 2003). R. Foster, Office of the Actuary, CMS, *Rough Estimates of Increase in Net Medicare and Other Federal Costs Under Selected Draft Senate Finance Proposals* (June 11, 2003); see also D. Rogers, "Fever Is Rising in Drug-Bill Imbroglio," *Wall Street Journal* (May 4, 2004): A2; S.G. Stolberg & R. Pear, "Mysterious Fax Adds to Intrigue Over the Medicare Bill's Cost," *New York Times* (Mar. 18, 2004).

[8] On January 23, 2004, the Congressional Budget Office wrote to the Senate Majority Leader Frist to say that removing the "noninterference" provision would "have a negligible effect on federal spending." D. Holtz-Eakin, Director of the Congressional Budget Office, Letter to the Honorable Ron Wyden (Mar. 3, 2004).

[9] M.B. McClellan, Speech Before the First International Colloquium on Generic Medicine (Sept. 25, 2003) www.fda.gov/oc/speeches/2003/genericdrug0925.html. The speech was widely reported. See, e.g., C. Bowe & G. Dyer, Americans Lured By Lower Prices, Financial Times 17 (May 5, 2004) ("The rhetoric intensified in September when Mark McClellan, then head of the FDA, attacked European drug price controls and said other rich nations should pay more of the development cost for drugs."). See also M.W. Serafini, Drug Prices: A New Tack, 36:16 National Journal (Apr. 17, 2004) ("So [House Speaker] Hastert and [Senator] Kyl championed the novel idea that the key to lowering U.S. prescription drug prices is to persuade foreign governments to raise their prices…The idea of trying to level the international playing field on prescription drug pricing originated with the U.S. pharmaceutical industry. But Hastert and Kyl played significant roles last fall in persuading the Bush administration to embrace this strategy…The result

Australian prices are economically efficient and the appropriate targets of reform are excessive US prices.

3. This FTA Will Be Used As A Model To Increase Drug Prices Worldwide

Ralph Ives was the chief US negotiator of the FTA. After his success in Australia, he was promoted in April 2004 to the newly-created post of Assistant United States Trade Representative for Pharmaceutical Policy. In his new post, he will attempt to raise patented drug prices throughout the OECD through trade agreements,[10] even though it is not clear that higher prices are necessary to pharmaceutical innovation.[11]

4. US Consumers Will Not Benefit From Higher Australian Drug Prices and Blocked Drug Exports

There is no guarantee that US consumers will benefit from higher drug prices in Australia. Drug companies are under no obligation to lower US prices as Australian prices increase.

Press reports indicate that under the FTA, Australian negotiators 'gave assurances' that low-cost drug exports to the US would be blocked, despite legislation in Congress to specifically permit importation from Australia.[12] The FTA is being used to block Congressional attempts to give Americans access to low-cost drugs.

5. Transparency

We are told that the FTA is needed to promote 'transparency' in the PBS process.[13]

If transparency is the goal, let me suggest the first place to start: publicly release all of the submissions to the relevant PBS committee, the PBAC. Policymakers worldwide would benefit from seeing all of the data previously collected. If drug companies think they've been unfairly treated, then the debate can proceed publicly. Today, PBAC data is secret ('commercial in-confidence') because the drug companies demand secrecy.

---

was the United States' first free-trade agreement that included modest concessions on pharmaceutical price controls.").

[10] A clear outline of the Bush Administration's pharmaceutical trade agenda can be found in the testimony of Grant D. Aldonas, Under Secretary of Commerce for International Trade, to the US Senate Finance Committee on April 27, 2004.

[11] K. Outterson, Pharmaceutical Arbitrage, 6 Yale Journal of Health Policy, Law & Ethics (pending, Dec. 2004) (discussing the concept of *globally optimal patent rents* in the context of pharmaceutical innovation).

[12] Bill Condie, *Glaxo Dismisses Free Trade Concerns*, Evening Standard (London), June 14, 2004 ("Australian negotiators have also given assurances that re-importation of drugs to the US would be banned").

[13] Office of the United States Trade Representative, Free Trade 'Down Under:' Summary of the U.S.-Australia Free Trade Agreement (Feb. 8, 2004): 3 ("In implementing these principles, Australia will make a number of improvements in its Pharmaceuticals Benefits Scheme (PBS) procedures – including establishment of an independent process to review determinations of product listings – that will enhance transparency and accountability in the operation of the PBS.")

Release the data publicly and allow the world to see the economic evaluations. Let the world see all of the clinical data on which drugs are truly innovative, and which ones offer modest or no improvements.

Second, transparency should require drug companies to disclose all financial relationships with researchers and policymakers. The US National Institutes of Health is currently embroiled in a major controversy as we are just beginning to understand how profoundly PhRMA influences research.[14] We need to see if the researchers touting drugs are truly independent. All of this is absent from the FTA.

Third, if transparency is needed, they why were health care NGOs excluded from the Advisory Committees to the FTA? The key committee on this issue, ISAC-3, included representatives of the pharmaceutical industry, but not groups critical of extending TRIPS Plus rules to drugs. On this issue, Australian and American representatives of drug companies negotiated with themselves, while NGOs were shut out.

Fourth, will transparency apply to the new Medicines Working Group under the FTA? Who will be appointed? Will those meetings be open to the public? Will NGOs be permitted to participate? Will past and present conflicts of interest be disclosed?

Fifth, the very concept of 'transparency' is laughable in a Free Trade Agreement exceeding a thousand pages in length. This is a frightfully complex agreement, with minutely negotiated provisions that are very difficult for even trade lawyers to understand.

For example, when the US stood against the world to attack unlicensed generic anti-retroviral drugs for AIDS, it was the 'public health' language of the WTO TRIPS agreement which rallied the world against the US and eventually led to the concessions at Doha and Cancun.[15] In the FTA, the 'public health' language is missing, replaced by other language supporting 'pharmaceutical innovation.' In the future, when the US invokes the FTA dispute resolution mechanism, a panel of highly specialized trade experts will decide whether Australia's efforts to reform the PBS satisfy the FTA. To these experts (several of whom may have participated in the negotiations), the absence of the TRIPS public health language and the additional provision on pharmaceutical innovation will be viewed as very significant. Australia could well lose a panel decision on such a basis, allowing a Government to plead years from now that its hands are tied by the FTA. I suspect that the FTA includes many other subtleties. It will take some time to find them all.

Finally, a call for transparency should be received with a little skepticism from an industry with incredibly complex and opaque pricing and business practices, including

[14] National Institutes of Health, Report of the National Institutes of Health Blue Ribbon Panel on Conflict of Interest Policies (Draft, May 5, 2004): 1-5.
[15] See, e.g., Ellen 't Hoen, TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha, 3 Chicago Journal of International Law 27 (2002).

the practice of blocking publication of clinical studies which demonstrate problems with their products.[16]

* * * * * *

In my home state of West Virginia, we are exploring a drug reimbursement system which includes economic evaluation. We will ask the drug companies for copies of the work already completed for the PBAC. Other states are exploring similar programs. If Australia can maintain the PBS for a few more years, it will be hailed as a model in the United States. This is both my hope and PhRMA's fear. Undermining Australia's PBS is an inappropriate topic for a free trade agreement.

[16] See, e.g., Barry Meier, A.M.A. Urges Disclosure on Drug Trials, New York Times, June 16, 2004. Two days later, Merck announced plans to voluntarily disclose data. Barry Meier, Merck Backs U.S. Database to Track Drug Trials, New York Times, June 18, 2004.